Applicant: Denny, et al. Attorney Docket No.: 19644-005US1

Serial No.: 10/551,612

Filed : July 26, 2006 (§ 371(c)(1,2,4) date)

Page : 2 of 21

## IN THE SPECIFICATION

Please amend the specification as follows.

Please replace paragraph beginning at page 17, line 4 with the following amended paragraph:

U.S. Patent Publication No. 29093/0040009 2003/0040009 A1 to Denny et al., which is incorporated herein by reference, describes the relationship of mucin concentration to DFT (decayed and filled permanent teeth). The mucin test, as described in U.S. Patent Publication No. 29093/004099 2003/0040099 A1, comprises first separating a salivary mucin, e.g., MUC7 mucin, from all other sialic acid-containing molecules in the saliva, by known methods such as sodium dodecylsulfate-polyacrylamide gel electrophoresis (SDS-PAGE). The sialic acid attached to the mucin is then quantitated and reported.

Please replace paragraph beginning at page 21, line 23 with the following amended paragraph:

FIG. 2 describes a linear regression anayleis analysis of DFT versus the sum of independent variables (MAL I, JAC, MAA, MUC7 mucin, MUC5B mucin, gender, and age) for forecasting DFT with representative 98% confidence levels.

Please replace paragraph beginning at page 21, line 26 with the following amended paragraph:

FIG. 3 describes a linear regression analyses analysis for the relationship between MUC7 mucin alone and DFT with representative 98% confidence levels for the same subjects analyzed in FIG. 2.

Please replace paragraph beginning at page 22, line 3 with the following amended paragraph:

FIG. 7 describes a linear regression analyses analysis of DFT versus the sum of independent variables (MAL I, JAC, SNA, ethnicity, and age) for forecasting DFT with representative 96% confidence levels.

Applicant: Denny, et al. Attorney Docket No.: 19644-005US1

Serial No.: 10/551,612

Filed : July 26, 2006 (§ 371(c)(1,2,4) date)

Page : 3 of 21

Please replace paragraph beginning at page 22, line 25 with the following amended paragraph:

FIG. 18 describes a linear regression analysis of DFT versus the sum of quantitated lectin affinities with representative 96% confidence levels in a mixed group of children and adults.

Please replace paragraph beginning at page 22, line 28 with the following amended paragraph:

FIG. 19 describes a linear regression analyses analysis of risk level for children and young adults versus the sum of quantitated lectin affinities with representative 96% confidence levels

Please replace paragraph beginning at page 36, line 15 with the following amended paragraph:

The visible particles according to this invention are microparticles (i.e., a micrometersized particles) that can be directly visualized, such as a dyed particle. Any suitable insoluble particle may be employed for purposes of this invention, including, but not limited to, particles of a polymeric material which may include, but is not limited to, a thermoplastic (e.g., one or more of polystyrenes, polyvinyl chloride, polyacrylate, nylon, substituted styrenes, polyamides, polycarbonate, polymethylacrylic acids, polyaldehydes, and the like), latex, acrylic, latex or other support materials such as silica, agarose, glass, polyacrylamides, polymethyl methacrylates, carboxylate modified latex, Sepharose SEPHAROSE, methacrylate, acrylonitrile, polybutadiene, metals, metal oxides and their derivatives, silicates, paramagnetic particles and colloidal gold, dextran, cellulose, and liposomes, and natural particles such as red blood cells. pollens, and bacteria. The size of the microparticles used in this invention is selected to optimize the binding and detection of lectin-binding components of saliva, and are typically 0.01 to 10.0 μm in diameter and preferably 0.01 to 1.0 μm in diameter, specifically not excluding the use of either larger or smaller microparticles as appropriately determined. In one embodiment, the microparticle is substantially spherical in shape. The preferred microparticle in the present invention is composed of latex containing a colored dve.

Applicant: Denny, et al. Attorney Docket No.: 19644-005US1

Serial No.: 10/551,612

Filed : July 26, 2006 (§ 371(c)(1,2,4) date)

Page : 4 of 21

Please replace paragraph beginning at page 47, line 31 with the following amended paragraph:

The mucin test, as described in U.S. Patent Publication No. 20003/0040009

2003/0040009 A1, does not apply to all races or ethnicities. The present invention addresses this issue by providing a universal test which can forecast equally well the accumulated caries history, i.e., DFT (decayed and filled permanent teeth) among various races and age groups. For example, in one embodiment of the invention, the test forcasted equally well the accumulated caries history in Hispanic and Chinese 7-9 year-old children and in Asian and Caucasian 20-25 year-old adults.

Please replace the Abstract originally found on page 80 of the corresponding international application, and as published in U.S. patent application publication 2006/0263825, the publication of the instant U.S. application, with the following amended abstract (a clean copy of the amended abstract is provided on a separate sheet herewith):

Provided are methods, test devices, and diagnostic kits for predicting, assessing, and diagnosing the risk of a disease using salivary analysis. The method comprises methods comprise providing a whole (unfractionated) saliva sample from a subject; contacting an aliquot of [[said]] the saliva with [[one]] two or more lectins under conditions that allow [[said]] the [[one]] two or more lectins to bind to a lectin-binding component of [[said]] the saliva; detecting the amount of bound lectin; and comparing the amount of bound lectin to the amount known to bind a saliva sample from a control patient, to predict the risk of a disease in the subject. Also provided are methods for reducing the risk of a disease and a method for assessing the risk of the disease at a defined level.